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(12) UK Patent Application (19) GB (11) 2 288 686 (13) A

(43) Date of A Publication 25.10.1995

(21) Application No 9507522.2

(22) Date of Filing 11.04.1995

(30) Priority Data
(31) 9407936 (32) 21.04.1994 (33) GB

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(51) INT CL[6]
G09B 23/28

(52) UK CL (Edition N)
G5G G4 G5A

(56) Documents Cited
None

(58) Field of Search
UK CL (Edition N) G5G G16 G17 G4
INT CL[6] G09B 19/00 23/00 23/28

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(54) Medical Training Device and Method

(57) The device (10) for simulating medical procedures comprises an instrument (12) movable by a user to practise the procedure, an actuator (16) connected to the instrument (12) to provide a force or resistance to the instrument to simulate the procedure, the force provided by the actuator being controlled by a controller (24). Sensors (14) detect values representative of the force, displacement and/or velocity of the instrument, the sensors communicate these values to control means (18) capable of receiving said values and including means to compare them with reference values (22) to determine force, displacement and/or velocity demands. The controller (24) is connected to the control means (18) and the actuator (16), the controller being capable of receiving the demand(s) and, where appropriate, instructing the actuator to vary the force provided to the instrument (12).

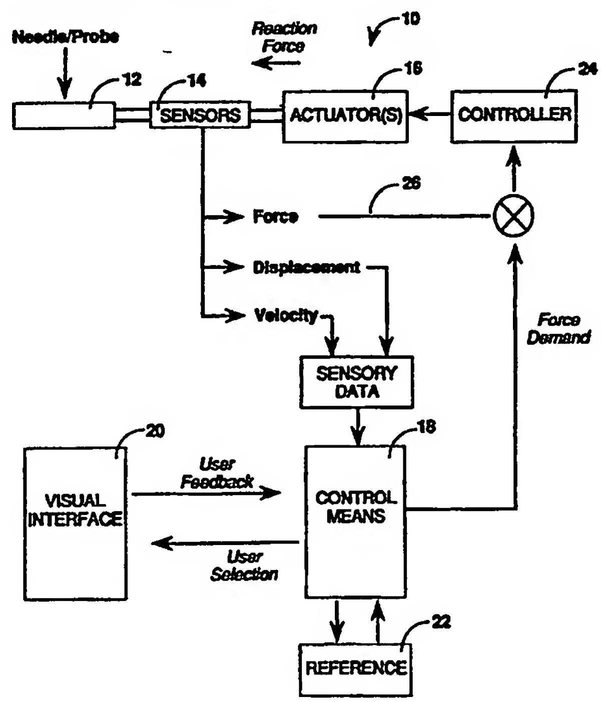

Figure 2

At least one drawing originally filed was informal and the print reproduced here is taken from a later filed formal copy.

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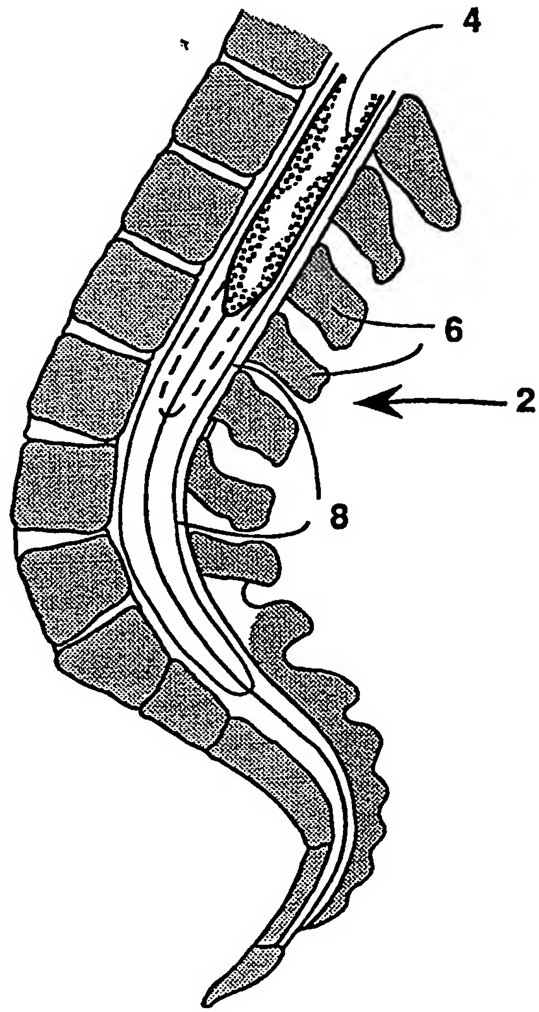


Figure 1

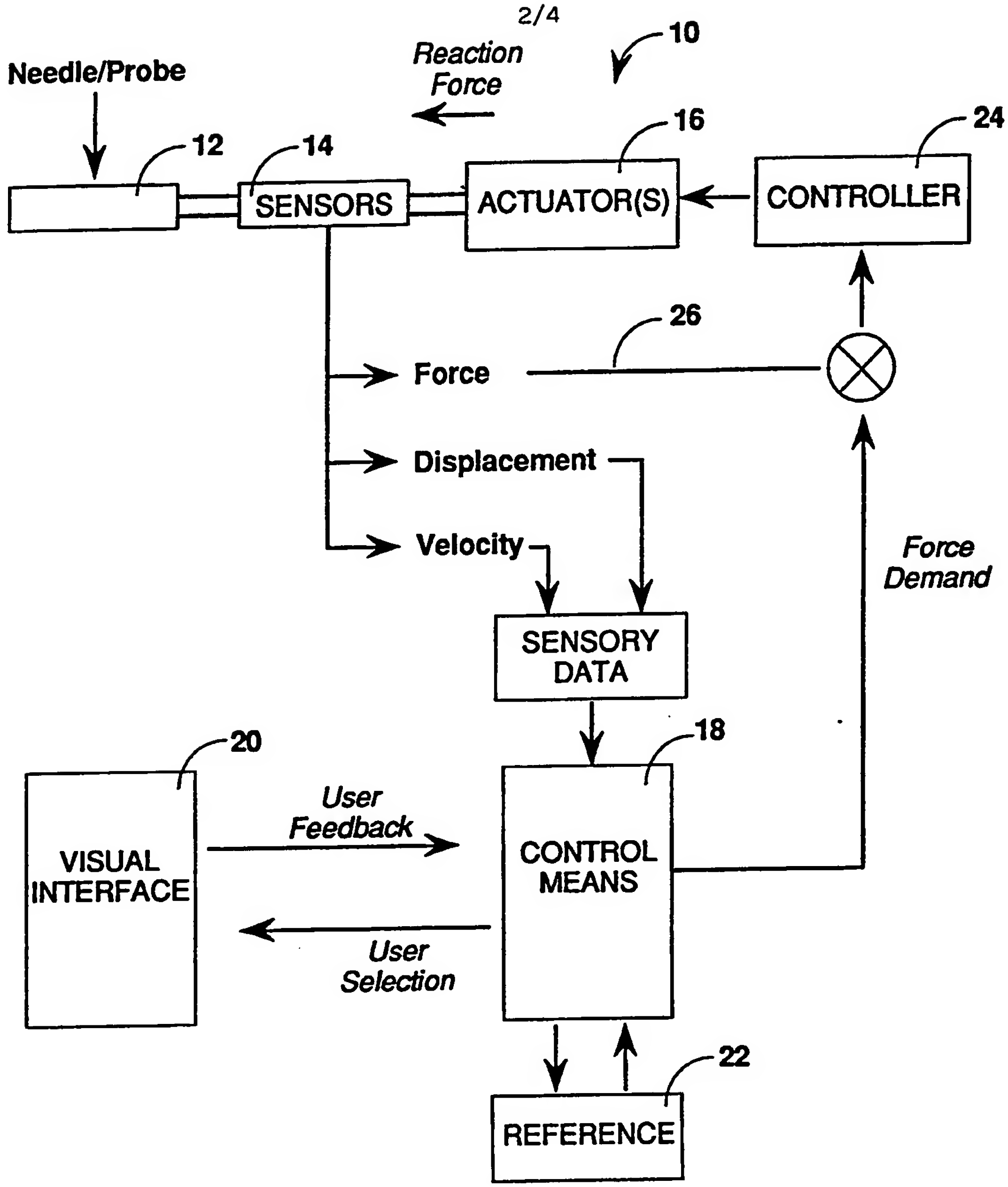

10
Needle/Probe
Reaction Force
12
14
16
24
SENSORS
ACTUATOR(S)
CONTROLLER
26
Force
Displacement
Velocity
Force Demand
SENSORY DATA
20
18
VISUAL INTERFACE
User Feedback
CONTROL MEANS
User Selection
22
REFERENCE

Figure 2

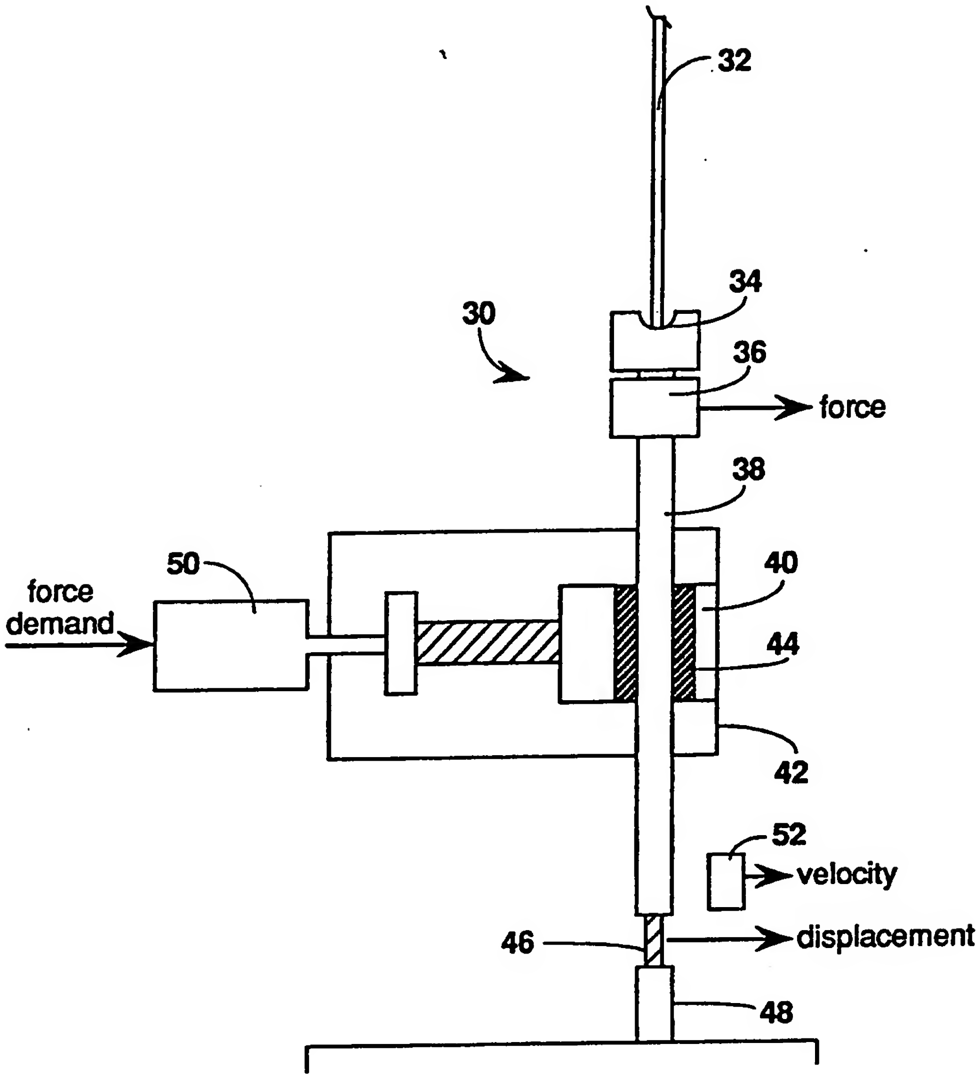
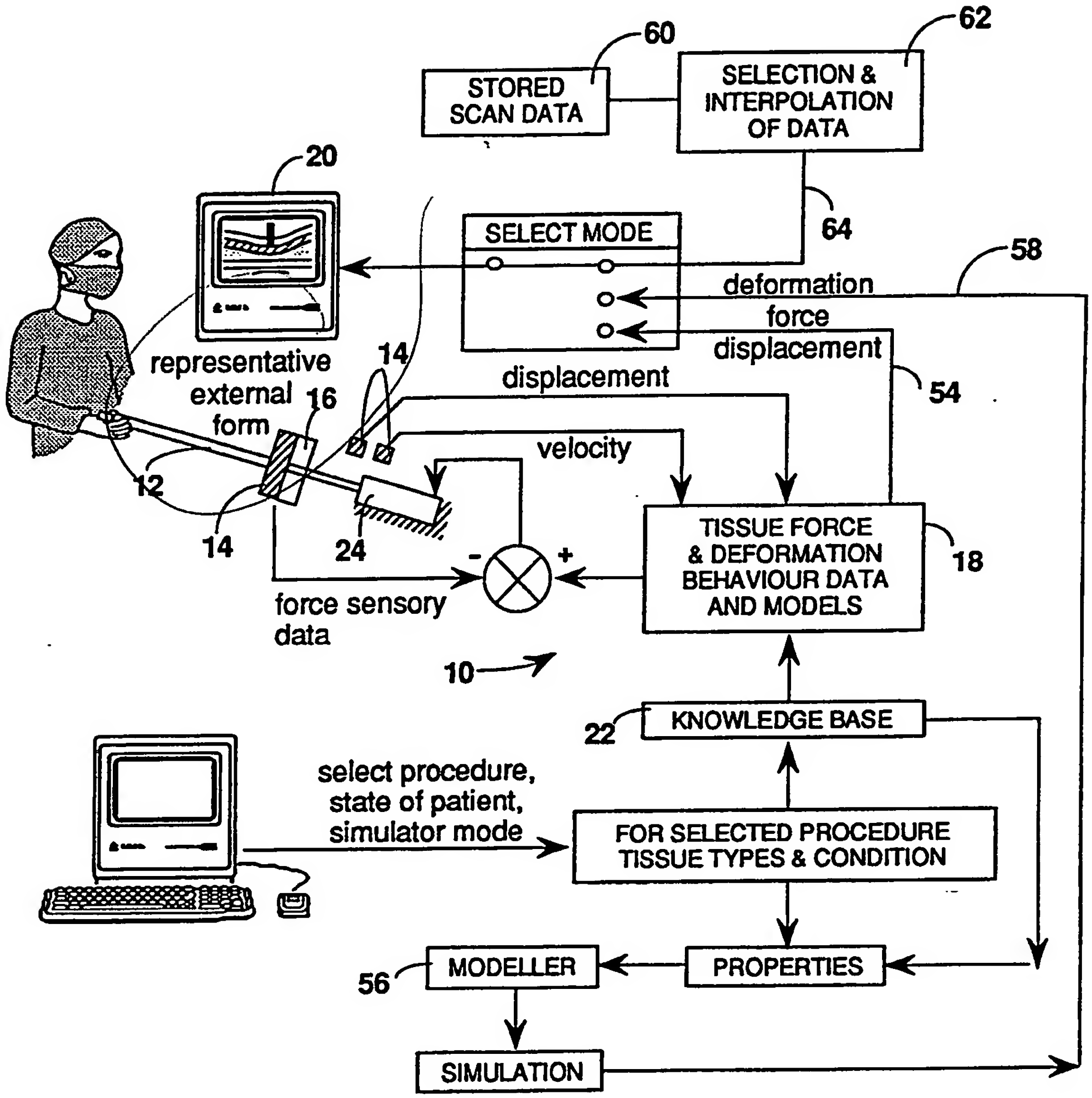

32
34
30
36
force
38
50
force
demand
40
44
42
52
velocity
46
displacement
48

Figure 3



60
62
STORED SCAN DATA
SELECTION & INTERPOLATION OF DATA
20
64
SELECT MODE
58
deformation
force
displacement
representative external form
14
16
displacement
54
velocity
12
14
24
TISSUE FORCE & DEFORMATION BEHAVIOUR DATA AND MODELS
18
-
+
force sensory data
10
22
KNOWLEDGE BASE
select procedure, state of patient, simulator mode
FOR SELECTED PROCEDURE TISSUE TYPES & CONDITION
56
MODELLER
PROPERTIES
SIMULATION

Figure 4

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MEDICAL TRAINING DEVICE AND METHOD

The present invention relates to a training device, and in particular to a device for training users in medical procedures, and a method of using the device.

The human body consists of a variety of layers of tissue types including skin, muscle, fat, ligaments, soft tissue, membranes, fluids, tendons and bone. The thickness, flexibility and resistance offered by these various layers making up the human body to penetration by probes, needles and other tools varies between patients, being dependent on factors such as build and age. This variability can make it difficult for a medical practitioner to judge the distance and force required to carry out the procedure, such as inserting a needle or other tool into the human body. As these media are variable and compliant, in practice the medical practitioner uses tactile feedback to estimate the state of penetration and to determine when the tool being used is in the correct position.

By way of example, in techniques such as epidurals, soft tissue biopsies and injections, the medical practitioner has to precisely control the penetration of a needle into the appropriate body space through tough membranes. In many cases, the medical practitioner needs to react quickly once perforation of the membrane has occurred, to minimise the protrusion of the needle through the membrane. For example, in performing a lumbar puncture, a needle is inserted through various tissues into the extra dural space close to the spinal cord, for example to inject analgesic for an epidural.

In a dural puncture, although the distance the needle must be inserted before the extra dural space is reached is remarkably constant in the average individual, it is much more difficult to estimate in an obese patient. Gutierrez (Gutierrez, 1939) in a personal series of 3,200 cases, found that the distance varied from 2.5 to 8 cm, but in 80% of this large series the range narrowed down to 4 to 5 cm. The increased depth in obese people is due primarily to the fat in the subcutaneous tissue, but also depends on the angulation of the needle. Thus, if the needle happens to go in almost at right angles, the depth will be much less than if it has to be angulated steeply to avoid the lamina.

However, the procedure is further complicated as damage to the spinal cord must be avoided. In the adult male, the spinal cord varies in length from 42 to 45 centimetres and generally ends at the lower border of the 1st lumbar vertebra. However, research has shown that this was true in only 50% of the sample examined. In 94% of the cases the spinal cord ended opposite either the 1st or 2nd lumbar vertebra. Of the others, five finished opposite the thoracic and three as low as the 3rd lumbar vertebra.

The above example is illustrative of the type of factors that must be taken into account by the medical practitioners in order to achieve a successful end result in many medical procedures that use this type of tactile feedback. Thus, techniques such as dural punctures can be surprisingly difficult to carry out and require a high degree of skill and experience.

Whilst it is possible to practice on cadavers, unfortunately the tissues of a cadaver provide different tactile characteristics to live tissues. Therefore, real experience in the use of these techniques has up until now been gained by performing them on live patients.

The increasing use of these techniques, and others such as Chorion Villa Biopsies (which extracts samples of fluid from the womb and the placenta during pregnancy in order to determine abnormalities), lumbar cerebrospinal fluid drainage (which is sometimes used during intracranial aneurysm surgery) and many other similarly administered procedures involving the application of local anaesthetics, most notably in the orbit (the eye cavity) in eye surgery, is resulting in a greater possibility of damage to the patient from an inexperienced practitioner.

Broadly, the present invention provides a device for simulating medical procedures and method of using the device for training medical practitioners in techniques such as biopsies, epidurals, injections and other delicate and precise penetrations in soft tissues, without having to use live subjects, with the risk that that entails. Thus, the present invention allows the practitioner to experience the tactile sensation of carrying out different medical techniques that is essential to determine the progress of the needle, probe or other tool.

Accordingly, the present invention provides a device for simulating medical procedures comprising:

(a) a user interface movable by a user to practise

the procedure;

(b) an actuator connected to the user interface to provide a force or resistance to the user interface to simulate the procedure, the force provided by the actuator being controlled by a controller;

(c) sensor means to detect values representative of the force, displacement and/or velocity of the user interface, the sensor means including means to communicate these values to control means;

(d) control means capable of receiving said values and including means to compare them with reference values to determine force, displacement and/or velocity demands; and,

(e) a said controller connected to the control means and the actuator, the controller being capable of receiving the demand(s) and, where appropriate, instructing the actuator to vary the force provided to the user interface.

Thus, the behaviour of tissues during different medical techniques can be simulated in response to the force applied during the insertion of tools into the tissue. This simulation allows the medical practitioner to experience and learn how to carry out these procedures without the necessity of using live patients.

In addition, the device can allow medical practitioners to experience the natural variation that occurs between patients, and to experience unexpected conditions, such as the presence of a defect, growth or bone, that might be encountered during the course of different techniques.

The present invention includes a method of simulating a medical procedure for a user comprising the steps of:

(a) the user moving a user interface to practise the procedure, the user interface having a force or resistance applied to it to simulate the procedure;

(b) measuring values representative of the force, displacement and/or velocity of the user interface using sensor means and communicating said values to control means;

(c) the control means receiving said values and comparing them with reference values, determining force, displacement and/or velocity demands and communicating the demand(s) to a controller; and,

(d) the controller receiving said demand(s) and, where appropriate, instructing the actuator to vary the force provided to the user interface.

The training device and method of using it can be used not only by doctors, but also by students, nurses, general practitioners, dental staff, anaesthetists and veterinarians to either gain experience initially or to refresh their skills.

In this context, the term "user interface" (a) means the tool used to perform the medical procedure, for instance a needle, probe or scalpel, or a device intended to create similar tactile feedback so that the user experiences the same sensation as using the actual tool. This helps to make the simulation as close to real life as possible.

As indicated above, the user interface is connected to an

actuator to provide the appropriate resistance to the interface to simulate the medical procedure. In the case of a needle, this will simulate the penetration of different layers of tissue to a target area and will involve the need to provide resistance to the movement of the needle in one dimension. In the case of a scalpel to simulate cutting through layers of tissue, the actuator will need to provide resistance to the movement of the scalpel in two or three dimensions. Tools used in minimal invasive (or "keyhole") surgery are generally provided with operating handles rather like those of scissors and are operated using three types of movement could be usefully simulated; translation in one direction, a rotation about the direction of translation and a squeezing action, eg to simulate the action of forceps. This might be simulated using a pair of finger receiving apertures, having walls through which the user can apply force to simulate carrying out the procedure and receive tactile feedback from the actuator. This force can be generated by varying the pressure of fluid in a space between the apertures.

The actuator (b) has to provide a resistance to the user interface which is capable of being varied to simulate the feel of different tissues. As an example, in the case of user interface which is a needle, this can be achieved by gripping the actuator between the jaws of a vice, with the movement of the jaws varying the tightness of the grip on actuator. The user then inserts or otherwise applies the end of the needle to the actuator to practise the procedure. Alternatively, the needle might be constrained by a nut on a ball screw or lead screw, with rotation of

the screw, and hence also axial motion of the needle, being controlled by a motor drive.

In this example, the feel of the simulation can be enhanced by lining the jaws of the vice with a material having the appropriate frictional characteristics to simulate the penetration of the needle through different layers of the body. For instance, rubber can be used to provide a soft and slippery feel. Alternatively, a piston and cylinder arrangement, fluids whose viscosity can be varied electrostatically or magnetic components could be used to allow the force or resistance applied to the user interface by the actuator to be varied.

Alternatively, in the simulation of minimal invasive surgery techniques mentioned above, the actuator can provide tactile feedback by varying fluid pressure between the finger receiving apertures of the user interface.

The sensor means (c) used to measure the force, displacement and/or velocity of the user interface can be of standard types known in the art, eg a force transducer to measure force or a potentiometer to measure displacement. Although it is only necessary to directly measure some of these variables, and to calculate the values of the remaining variables from the measured ones, this is not preferred as the error associated with calculated values is, in general, greater than the error incurred in measuring values directly.

Preferably, the force measurement is used in a feedback

loop to the controller to help correct discrepancies between the intended and actual operation of the actuator, so as to make the device self-correcting.

The sensory data (force, velocity, displacement) from the simulation is communicated to control means (d) to compare against reference values for a given simulation. Typically, the control means will be a computer programmed with a model or algorithm to allow the calculation of force, velocity or displacement demand(s) from the sensory data, a reference database containing data gathered for the medical procedure being simulated or a hybrid of these approaches. Conveniently, the data for a given technique can be gathered from experimental measurements on patients or cadavers, providing the reference values for the database or on which to base a model.

Once the control means have compared the actual movement of the user interface against the reference values, the force, displacement and/or velocity demands can be calculated, depending on the progress of the user in carrying out the technique. The demand(s) are then communicated to the controller (e), which can instruct the actuator to act on the user interface, eg by exerting a force, if it is necessary to do this.

Preferably, the device additionally comprises some form of visual feedback so that the user can assess how he or she is performing, especially in relation to the correct way to carry out the technique. This allows the user to learn or practise the technique by comparison with the way experts

carry it out. The visual feedback may be a picture on a monitor, or may be more sophisticated, for example involving virtual reality techniques.

In one approach, the visual feedback takes the form of a graph, eg of force against time, so that the user can see how one or more of the parameters he or she is applying to the user interface during the simulation compares to that applied by an expert carrying out the same procedure. Preferably, force is the parameter displayed on the visual interface as it is a sensitive indication of the movement of the user interface during the simulation.

In a second approach, a mathematical model of the properties of tool and tissues used in a given medical procedure can be used to generate a picture of medical procedure on a screen. The deflection of the tissue and/or the movement of the tool can then be simulated as the procedure progresses, and the picture on the screen updated so that the user can follow the effects of his or her actions.

In a third approach, the picture provided on screen can be derived from pictures of a real procedure being carried out, the pictures being selected according to the progress of the procedure and interpolated together to provide a continuous visual indication of the progress of the simulation. This approach has the advantage that the visual feedback the user experiences corresponds closely to the feedback in real life. Thus, for example, where ultrasound images are used to position a needle in a

procedure, it is desirable for the user to get used to viewing and interpreting these images as part of the simulation. In this approach it may be convenient to update some parts of the picture more rapidly than others, which can remained essentially fixed as background.

Combinations of the above three approaches can be used to provide the user with different types of feedback to learn from.

While the individual elements comprising the device are known in the art for different applications , eg monitoring mechanical systems, they have not been applied to simulating the complex, variable and compliant materials found in the human body.

In addition, the control system described above can be used to determine the force, velocity and translation of a user interface and use these to move to a tool remote from the interface in a real, rather than a simulated, procedure. This is sometimes referred to a telemanipulation or telesurgery. The training device described above could be readily modified to operate in this way by the skilled person, eg using the velocity of the user interface to instruct a servo to move a tool during a procedure, and measuring the force encountered by the tool to generate a force demand that can be applied to the user interface to provide tactile feedback to the medical practitioner.

By way of example, the present invention will now be described with reference to the following drawings in

which:

Figure 1 shows a cross-section through the human body showing the structure around the spinal cord;

Figure 2 shows a flow diagram indicating how the different elements comprising the present invention interact;

Figure 3 shows schematically an example of a device for simulating injections and biopsies; and,

Figure 4 shows a flow diagram indicating how different forms of visual feedback can be incorporated into arrangement shown in figure 2.

Figure 1 shows the structure of the region 2 immediately surrounding the spinal cord 4. In carrying out an epidural, a needle has to be inserted through layers of skin and ligament (not shown), to pass between vertebrae 6 to reach the extra dural space 8 and inject analgesic. All these layers have different resistances to penetration, and consequently feel different to the practitioner carrying out the epidural.

However, in performing an epidural, once the extra dural space 8 has been penetrated, the person carrying out the technique has to prevent further penetration of the needle, to avoid damage to the spinal cord 4.

Figure 2 shows a device 10 for simulating a medical technique comprising a user interface 12 for the user to manipulate and sensors 14 to detect the force, displacement and velocity of the user interface 12. The resistance to the movement of the interface 12 is provided by actuator(s)

16, to simulate the movement of the needle or probe through different layers of tissue in carrying out the technique.

The sensors 14 provide values of force, displacement and velocity to control means 18. The control means 18 are then able to compare these experimental values with a reference 22, typically a computer programmed with a database containing reference values, or a model or algorithm to calculate reference values or a combination of these.

The control means 18 are also linked to a visual interface 20, for example a monitor, to provide the user with an indication of the progress of the simulation, based on the movement of the user interface 12 . The visual interface 20 can also be used to provide instruction as to the correct way to carry out the technique, so that the user can see whether he or she is carrying out the technique correctly and knows what to do at each stage of the simulation.

The control means 18 are in communication with a controller 24, which instructs the actuator(s) 16 as to the reaction force to offer to the user interface 12 to simulate the medical procedure being practised. The controller 24 also receives force data from the sensors 14 in a feedback loop 26, thereby helping to reduce error in the system.

In use, the user selects a technique to practise from those on offer and practises the technique by moving the user interface 12. The movement of the user interface 12 and

the force applied to the actuator(s) 16 are measured by sensors 14 and the results communicated to the control means 18. The control means 18 then compares the sensory data against the reference 22 and, if appropriate, provides a force demand to alter the force provided by the actuator(s) 16. The sensory data can also be used to generate a visual indication of the simulation on the visual interface 20. The above cycle of measurement, comparison with a reference and adjustment of conditions can be repeated until the simulation is completed.

The user interface 12 of the device 10 is movable in one dimension, ie has one degree of freedom. However, the device could be adapted to simulate techniques in two or three dimensions, for example simulating the use of a scalpel to cut selectively through layers of tissue.

Figure 3 shows a device 30 for simulating the resistance experienced in carrying out injections. A needle 32 is received in a recess 34 provided on a force transducer 36. The force transducer 36 is linked to one end of a rod 38, the rod being held between the jaws 40 of a vice 42. The jaws 40 of the vice are lined with rubber 44 to give them a soft and slightly slippery feel. Thus, when the needle 32 is pushed against the recess 34, the movement of the rod 38 feels similar to the movement of a needle through tissue.

The rod 38 is provided at its other end with a spring loaded position sensor 46, to detect the displacement of the rod 38, and a servo 48 to allow the position of the rod

38 to be varied. The resistance offered to the needle 32 can be varied by altering the grip of the jaws 40 of the vice 42, using servomotor 50.

The velocity of the rod 38 (and hence the needle 32) is detected using velocity transducer 52. The velocity of the needle 32, together with force data from the force transducer 36 and displacement data from the position sensor 46, is communicated to a computer (not shown), where these values can be compared against reference values derived experimentally or calculated from a model. The computer can then calculate whether the force applied to the rod 38 by the jaws 40 needs to be varied. If this is the case, the computer can instruct a force demand to the servomotor 50 to change the resistance offered to the rod 38 by the jaws.

As discussed above, the device 30 preferably also comprises means to provide the user with visual feedback of the progress of the technique, possibly allowing the user to compare his or her technique against that of a expert.

Figure 4 shows a flow diagram of a training device that is broadly similar to that shown in figure 2. In this figure, a visual interface 20 is provided that can display information on the progress of the procedure selected from one or more of three sources. Firstly, the visual interface can display the force or displacement of the user interface during the procedure, see reference 54, eg for comparison with values obtained by an expert. Secondly, a modeller 56 can be used to determine the deflection of

tissue caused by movement of the interface, and use this information to generate a picture so the user can gauge his or her progress. This is supplied via input 58. Thirdly, the picture provided on screen can be derived from stored data 60 of a real procedure being carried out, the pictures being selected 62 according to the progress of the procedure and interpolated together to provide a continuous visual indication of the progress of the simulation. This information is communicated to the visual interface 20 via input 64.

CLAIMS:

1. A device for simulating medical procedures comprising:

(a) a user interface movable by a user to practise the procedure;

(b) an actuator connected to the user interface to provide a force or resistance to the user interface to simulate the procedure, the force provided by the actuator being controlled by a controller;

(c) sensor means to detect values representative of the force, displacement and/or velocity of the user interface, the sensor including means to communicate these values to control means;

(d) control means capable of receiving said values and including means to compare them with reference values to determine force, displacement and/or velocity demands; and,

(e) a said controller connected to the control means and the actuator, the controller being capable of receiving the demand(s) and, where appropriate, instructing the actuator to vary the force provided to the user interface.

2. A device according to claim 1 wherein the user interface is a tool used to carrying out the procedure or a device that has similar tactile feedback characteristics.

3. A device according to claim 1 or claim 2 wherein the control means is a computer programmed with a model or algorithm to allow the calculation of the demand(s) from values detected by the sensor means.

4. A device according to any one of claims 1 to 3 wherein the sensors means are a force transducer to measure force and/or a potentiometer to measure displacement.

5. A device according to any one of the preceding claims wherein the device additionally provides a visual feedback to the user.

6. A method of simulating a medical procedure for a user comprising the steps of:

(a) the user moving a user interface to practise the procedure, the user interface having a force or resistance applied to it to simulate the procedure;

(b) measuring values representative of the force, displacement and/or velocity of the user interface using sensor means and communicating said values to control means;

(c) the control means receiving said values and comparing them with reference values, determining force, displacement and/or velocity demands and communicating the demand(s) to a controller; and,

(d) the controller receiving said demand(s) and, where appropriate, instructing the actuator to vary the force provided to the user interface.

7. A method according to claim 6 wherein the force measurement is used in a feedback loop to the controller to help correct discrepancies between the intended and actual operation of the actuator.

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Patents Act 1977
Examiner's report to the Comptroller under Section 17
(The Search report)

Relevant Technical Fields (i) UK Cl (Ed.N) G5G (G16, G4, G17) (ii) Int Cl (Ed.6) G09B (19/00, 23/00, 23/28) **Databases (see below)** (i) UK Patent Office collections of GB, EP, WO and US patent specifications. (ii)	Application number GB 9507522.2 Search Examiner R HOWE Date of completion of Search 1 JUNE 1995 Documents considered relevant following a search in respect of Claims :- 1-7

Categories of documents

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E: Patent document published on or after, but with priority date earlier than, the filing date of the present application.

&: Member of the same patent family; corresponding document.

Category	Identity of document and relevant passages	Relevant to claim(s)
	NONE	

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